INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2006/000755

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

C12Q 1/68 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) :
WPIDS, MEDLINE, CAPLUS, D-GENE, GenBank: bisulfite, cytosine, modif?, complex?, variabl?, simplify?; SEQ ID NO 1 of SEQ LISTING #51

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GenBank Acc. No. AF177040 Synthetic construct clone pH77(p7)-J6S hepatitis C virus, complete genome Yanagi, M. (*et al*) Virology 262 (1), 250-263 (1999) Hepatitis C virus: an infectious molecular clone of a second major genotype (2a) and lack of viability of intertypic 1a and 2a chimeras 100 % identity over 24 net (position 2241 to 2264 corresponding to SEQ ID NO 1: 2229-2252)	1
X	GenBank Acc. No. AF265005 Hepatitis C virus subtype 1a clone 9-8w6 polyprotein gene, partial cds Nousbaum, J. (*et al*) J. Virol. 74 (19), 9028-9038 (2000) Prospective characterization of full-length hepatitis C virus NS5A quasispecies during induction and combination antiviral therapy 91% identity (43/47) with 100% identity over 22 net (position 331 to 377 corresponding to SEQ ID NO 1:6588-6634)	1

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

" Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 August 2006	30 AUG 2006
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **INES CARRIN** Telephone No : (02) 6283 2435

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004 015139 A (EPIGENOMICS AG) 19 February 2004 See in particular page 5, lines 15-18 and page 19, lines 14-17	1
E	WO 2006 058393 A1 HUMAN GENETIC SIGNATURES PTY LTD) 8 June 2006 See pages 9, lines 12 to 28, p. 12, l. 6 to 18 and p. 34, l. 26 to p. 35, l. 35	1

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

please see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1 (partially: SEQ ID NO 1 in SEQ LISTING #51)**

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

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Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.
Note that Rule 13.2 states that where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The ISA has identified multiple separate inventions within the current claim set.

Each of the 107 independent claims are directed to modified nucleic acids from different micro-organisms.

The organism type cannot represent a special technical feature common to all the claims as the micro-organisms are not related. Hence there is a lack of unity **a priori.**

Furthermore, when considering the unity within each claim, it is appropriate to use the Markush approach. Although the sequences within a claim all have the common property that they are derived from a particular micro-organism, there is no common structure present in all of the sequences; and there is no single recognised class or group of compounds embracing all the sequences claimed. It is contrary to normal classification to group together such diverse sequences. Thus according to Markush, it is appropriate to classify each sequence as a separate invention. Therefore each claim represents **multiple** inventions.

Additionally, while the method of producing said sequences may represent a special technical feature, it appears that the methodology described in the specification is not new. For example, the modified nucleic acids were prepared by treating dsDNA with bisulfite to convert C residues to U residues (p.33-35). This was followed by an amplification process that converts U's to T residues (p.35-36). Thus the nucleic acids comprise residues A, T and G. A consequence of this process is that the nucleic acids derived from the upper and lower strands of the original dsDNA are no longer complementary.

Such a procedure is disclosed in the prior art document WO2004 015139. Specifically this document discloses reducing the complexity of nucleic acids by treating nucleic aid samples with bisulfite followed by amplification of the treated DNA. Bisulfite treatment converts C to U while the U is replaced by T during amplification. Thus converting a native nucleic acid into one containing A, T, G, U or A, T, G. Therefore the method of producing the claimed nucleic acids does not represent a common special technical feature within the meaning of Rules 13.1 and 13.2. Hence there is a lack of unity within each claim, **a posteriori.**

Furthermore, recognition of the value of using this approach to reduce DNA complexity for micro-organisms is also disclosed in WO2006 058393. As such the method of obtaining modified sequences using the methodology disclosed in the instant application does not represent a novel feature and cannot be regarded as a special technical feature to supply a unity of invention between each sequence.

As no additional fees were paid the International Searching Authority searched SEQ ID No 1 from Sequence Listing #51 (Claim 1), for the fee already paid.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO	2004015139	AU	2003266255	EP	1525328
WO	2006058393				

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX